Journal of Cosmetic and Laser Therapy. 2005; 7: 87–92

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ORIGINAL ARTICLE

Evaluation of a combined laser-radio frequency device (Polaris WR) for the nonablative treatment of facial wrinkles

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Abstract
Nonablative wrinkle reduction or skin tightening is desired by individuals who, ideally, hope to have the skin improvement associated with chemical or laser ablative techniques but without the undesirable recovery process. Electro-optical synergy (ELOS) technology that combines radio frequency (RF) and diode laser energy (900 nm) was used to treat 15 patients in this IRB sanctioned study. Energy settings were based on the depth of wrinkles (the greater the depth and concentration of wrinkles, the higher the RF setting) and ranged from 50–100 J/cm^2 RF and 15 J/cm^2 for the optical, laser component. Patients received three full-face treatments, and results were evaluated by comparison of standardized photographs and patient questionnaire given prior to each treatment and one month after the third treatment. The primary investigator and three other ''blinded'' physicians evaluated these photographs using Fitzpatrick's wrinkle classification to assess the improvement, if any, between the initial and final visit. Eight patients completed the study. Explanation for the exclusion of the remaining six patients were: one decided to have surgery, two felt the treatment was too painful, and three moved out of the area. Following treatment, all patients had mild swelling (resolved <48 hours) and skin hyperemia (resolved <24 hours). Results observed one month after the last treatment in eight patients demonstrated an average of 25% reduction in skin wrinkles (range 14%–32%). There were no adverse side effects. The major concern of the patients was the discomfort associated with the treatment. As part of an FDA investigation to assess efficacy, long-term follow-up was not a part of this study protocol.

Key words: *ELOS, laser treatment, non-ablative, radio frequency, wrinkle reduction*

Background

The ability to reduce wrinkles without a prolonged recovery time is desired by many patients. Individuals continue to seek a more permanent reduction in skin wrinkling not attainable with various skin ''fillers''. Many technologies have shown improvement in skin wrinkles/texture, including Coblation (1), laser (2–10) and chemical ablative technologies, longer wavelength devices (11–16) and intense pulsed light (IPL) (17,18). Treatment results vary depending on the clinical situation, operator experience and patient compliance. The selection of a particular technique centers on the balance between cost, efficacy and post-treatment recovery/morbidity. The common pathway of most treatment modalities that lead to wrinkle reduction and skin tightening is the inflammation that occurs in the sub-epidermal layers. Collagenisis is the by-product of this process as well as a modification in the elastin and epidermal layers (19,20).

An emerging technology for the nonablative treatment of skin laxity/wrinkles is RF. Unlike low frequency electrical current that causes muscle spasm and heat, current at 300 kHz and higher primarily produces a thermal effect in tissue. RF energy is blind to skin color classification and controlled by the electrical properties of the treated tissue. An additional benefit can be obtained if the RF energy can be optimally modulated/directed into a ''selective'' energy delivery system. Thermage Inc. has developed a promising utilization of RF energy called ThermaCool TC. Studies have shown a skin tightening effect in certain patients treated with this device (21). Syneron has developed a device that utilizes RF energy and, in addition, creates a synergistic effect with diode laser, ''optical'' energy in an attempt to optimize sub-epidermal heating and collagenisis without epidermal damage. This technology has been named ELOS (electro-optical synergy).

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(Received 11 March 2005; accepted 25 May 2005)

ISSN 1476-4172 print/ISSN 1476-4180 online
DOI: 10.1080/14764170500205826

The effectiveness of ELOS technology centers on the fact that tissue which is at a higher temperature conducts the electrical current and heats up faster than tissue at a relatively lower temperature. This is secondary to the fact that the higher the tissue temperature, the lower the impedance for RF current in a linear relationship. Therefore, by creating a localized increase in the temperature in the treatment zone (the dermis via the optical laser energy which penetrates into the deeper dermis), one may obtain a greater heating of the target tissue (dermis versus epidermis) exponentially based on the relationship that the conductivity of tissue is linearly dependent on its temperature, and Joule's law which predicts the heat generated by RF current. By creating a localized small tissue temperature increase with optical laser energy in the dermis, a larger temperature gradient is obtained in this selected, ''localized'' target tissue than for an identical RF tissue treatment without pre-heating. This is an extension of the process of selective thermolysis in which selected tissues (those that are pre-heated) are heated more than the surrounding tissue that has not been exposed to antecedent, optical energy. This pre-emptive optical heating can be tailored via its wavelength to select the exponential heating of the ''selected target'' chromophore. For superficial vascular lesions, the wavelength range of 570–590 nm is optimal for vascular pre-heating. For the Polaris WR, an optical wavelength of 900 nm was selected because of its penetration into the deeper dermal tissue. Because of the synergistic effect of the RF and laser energy, the amount of optical laser energy needed for a clinical effect is much lower than that required for devices of a similar wavelength that do not have the ancillary RF energy delivered to the tissue. This imparts a greater theoretical safety to this device.

To enhance the deep tissue selective effect and simultaneously provide epidermal safety, the Polaris WR device also pre-cools the epidermis. This mitigates any epidermal damage due to the heating of the deeper dermis. The bi-polar delivery handpiece creates a localized flow of RF energy from the active to the passive electrode within the handpiece and allows for treatment of the entire face excluding the eyelid skin. The flow of current reacts to the impedance of the tissue exposed to this RF energy source: the greater the tissue temperature, the lower the impedance, the greater the flow of energy and subsequent tissue heating. The cooling effect of the handpiece (-3°C) makes the epidermis relatively ''unattractive'' to the electrical energy (RF) and thus directs the RF energy to the lower impedance dermal tissue that has been pre-heated by the optical energy.

Methods

Fifteen patients were entered in this IRB approved study. Individuals who had a history of photosensitivity, or those taking medications that induce or are associated with a risk of photosensitivity, were excluded. Also excluded were patients taking aspirin or NSAID, using Accutane within six months prior to the initial visit, or requiring the use of a pacemaker or internal defibrillator. At a minimum, patients were required to have moderate wrinkles/skin laxity at rest. As part of this FDA submission protocol, six standardized photographs were taken at the initial visit, prior to each treatment, and then one month after the final treatment. Each patient received three full-face treatments with the Polaris WR device. External eye shields were used and the handpiece electrode contacts did not go internal to the bony orbital margin. Pain was controlled with a pre-treatment of oral Valium (10 mg) and/or Percoset (5 mg). No topical anesthetic agents were used. All patients received Polaris WR treatments with 15 J/cm^2 of optical energy. RF energy settings for these sessions were chosen based on the depth of wrinkles: fine wrinkles 50–70 J/cm^2, moderate depth 70–90 J/cm^2 and deep wrinkles 100 J/cm^2. The skin was hydrated with a thin coat of gel prior to handpiece contact. There was no immediate overlap of the antecedent treatment spot, and the entire face was treated 2–4 times/treatment session with a light pink skin color as the desired end point for session completion. Patients kept a diary of their subjective recovery.

Pre-treatment and one month following the last treatment photographs were shown, side by side, to three ''blinded'' plastic surgeons who were not informed of the technology being studied. The principal investigator also reviewed the side-by-side photographs and all used Fitzpatrick's scale of wrinkles/skin aging to record any difference observed. The patients' subjective assessments were summarized after their last visit.

Results

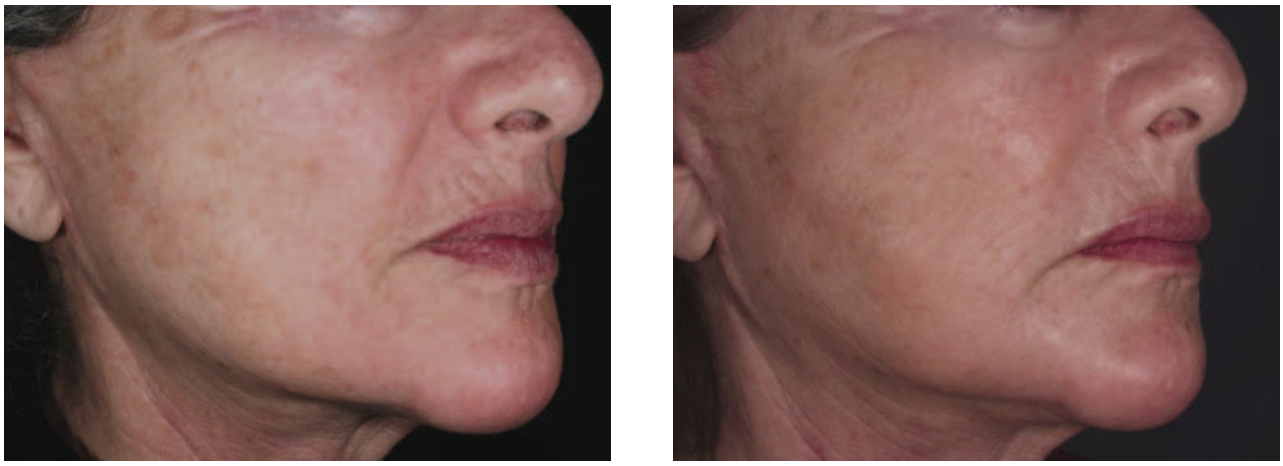
All patients treated were women. The average age was 58 years, range being 43–84 years. Treatment sessions lasted an average of 45 min/treatment. There were no complications associated with the treatments. Of the 15 patients, 6 did not complete the study. One patient decided to have surgery, two patients felt the treatment was too painful and three patients moved out of the area and did not have sufficient data for analysis. All patients felt the treatment was painful, with the amount of pain proportional to the RF energy delivered and the number of passes performed at each treatment session. In addition, for a given energy setting in an individual, discomfort was greater in areas with

less subcutaneous fat or over a bony prominence such as the zygomatic arch and forehead. Pain medication was not necessary after the treatment session as the discomfort experienced occurred during treatment.

All eight patients with sufficient data for analysis were deemed to have a reduction in wrinkles, by all of the evaluators. The average reduction in wrinkle scores was; 14%, 25%, and 32% for the three independent evaluators. The principal investigator felt there was a 30% average reduction in facial wrinkling. Using the improvement obtained with other treatment modalities as a comparison, the impact of ELOS treatment on wrinkles ranged from a CO_2 ablative treatment effect to a 20% TCA peel without the epidermal changes. Patients with perioral wrinkles had a significant clinical improvement. There was a generalized smoothening of forehead and cheek skin (Figures 1–4). Patients with significant dyschromia and wrinkles had a slight improvement in skin color (Figure 5). There was no perceptible improvement of undesirable hypervascularity of the skin. Facial hair was not reduced with this combination of optical and RF energy. Facial edema and post-treatment hyperemia resolved in 48 and 24 hours respectively after each treatment.

Conclusion

The Polaris device with ELOS technology appears to be another promising device for the nonablative reduction of skin wrinkles. Studies with a longer follow-up period will help define long-term efficacy. With the current optical energy wavelength, no improvement can be expected for undesirable vasculature. Further studies are necessary to define long-term efficacy and optimization of treatment parameters for skin tightening and wrinkle reduction. Assessment as to why there is a variable response at similar energy settings will provide subsequent patients a more predictable result. In this study, pain control was limited to the IRB



(A) (B)

Figure 1. This is a 65-year-old woman with minimal change in facial wrinkles but some improvement in the naso-labial fold and perioral region. A: before. B: 1 month after.

(A) (B)

Figure 2. This is a 62-year-old woman with a good improvement of significant rhytids of the cheek skin. A: before. B: 1 month after.

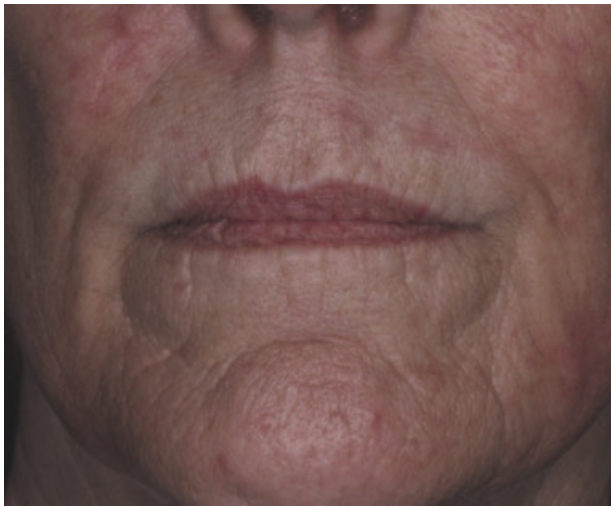
(A)

(B)

(C)

Figure 3. This is a 62-year-old woman with good reduction in the perioral wrinkles. She has maintained most of the improvement, six months after treatment. A: before. B: one month after treatment. C: six months after treatment.

(A)



(B)

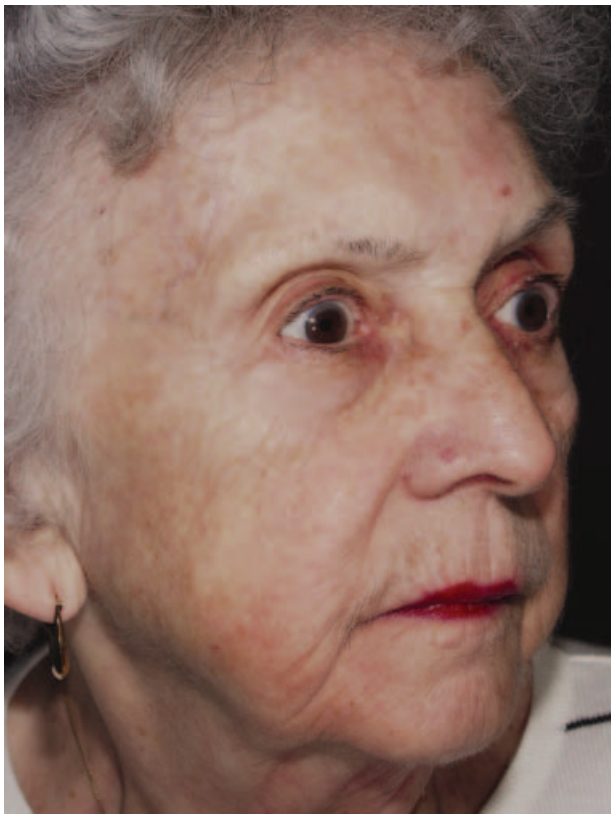
Figure 4. This is a 59-year-old woman with very good reduction in perioral rhytids. A: before. B: 1 month after.

protocol and was designed to avoid any potential skin change or modulation of the ELOS-cutaneous effect via topical skin pre-treatment. Following FDA approval of this device, subsequent patients have received nerve blocks, topical analgesic creams and/or topical air-cooling for pain control, and oral sedatives, with a significant reduction in discomfort during treatment without compromising the results.

This device appears to be ideal treatment option for darker skin types or for patients with tanned skin.

(A)

(B)



(C)

Figure 5. This is an 81-year-old woman who has significant facial rhytids, prominent naso-labial folds and dyschromia. All three were improved after three Polaris treatments, and the improvement was noticed at one and six months after her third treatment. A: before. B: one month after. C: six months after.

The laser optical energy has a relatively weak absorption of the chromophore melanin and the RF energy has no affinity to any color. The bi-polar delivery system provides a local current flow, permitting the safe treatment of difficult perioral wrinkles. The reusable handpiece allowed for customization of the number of passes required per treatment session to obtain the desired pink, skin color end point.

Disclosure

This study was funded by Syneron Medical as part of a multi-center investigation of this technology for FDA submission. Dr Kulick serves as a consultant for this company, teaches courses and receives compensation for these efforts.

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